



General

Guideline Title

ACR Appropriateness Criteria® radiologic management of benign and malignant biliary obstruction.

Bibliographic Source(s)

Ray CE Jr, Lorenz JM, Burke CT, Darcy MD, Fidelman N, Greene FL, Hohenwarter EJ, Kinney TB, Kolbeck KJ, Kostelic JK, Kouri BE, Nair AV, Owens CA, Rochon PJ, Rockey DC, Vatakencherry G, Expert Panel on Interventional Radiology. ACR Appropriateness Criteria® radiologic management of benign and malignant biliary obstruction. [online publication]. Reston (VA): American College of Radiology (ACR); 2012. 9 p. [82 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Owens CA, Funaki BS, Ray CE Jr, Brown DB, Gemery JM, Greene FL, Kinney TB, Kostelic JK, Lorenz JM, Millward SF, Nemcek AA Jr, Reinhart RD, Rockey DC, Silberzweig JE, Vatakencherry G, Expert Panel on Interventional Radiology. ACR Appropriateness Criteria® percutaneous biliary drainage in benign and malignant biliary obstruction. [online publication]. Reston (VA): American College of Radiology (ACR); 2008. 7 p.

Recommendations

Major Recommendations

ACR Appropriateness Criteria®

Clinical Condition: Radiologic Management of Benign and Malignant Biliary Obstruction

Variant 1: Initial therapeutic procedure for a patient with dilated bile ducts from benign biliary obstruction (e.g., choledocholithiasis).

Treatment/Procedure	Rating	Comments
Endoscopic internal biliary catheter	8	
Percutaneous internal/external biliary catheter	6	Most appropriate whenever endoscopic treatment is unsuccessful.
Surgery (transplant or hepaticojejunostomy)	2	

Treatment/Procedure	Rating	Comments
Medical management only	2	
Permanent biliary metallic stent	1	
Removable biliary covered stent	4	If the case involves a benign, postinflammatory stricture.
Endosonography-guided biliary drainage (ESBD)	4	
<u>Rating Scale:</u> 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Variant 2: Initial therapeutic procedure for a patient with elevated bilirubin and suspected sclerosing cholangitis.

Treatment/Procedure	Rating	Comments
Endoscopic internal biliary catheter	8	
Percutaneous internal/external biliary catheter	6	Depends on location and extent of stricture formation.
Surgery (transplant or hepaticojejunostomy)	2	Surgery rarely indicated except in cases of endoscopic and percutaneous failure.
Medical management only	6	
Permanent biliary metallic stent	1	
Removable biliary covered stent	2	
<u>Rating Scale:</u> 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Variant 3: Initial therapeutic procedure for a patient with malignant common bile duct obstruction (e.g., pancreatic carcinoma).

Treatment/Procedure	Rating	Comments
Endoscopic internal biliary catheter	8	
Percutaneous internal/external biliary catheter	7	
Surgery (transplant or hepaticojejunostomy)	5	May be appropriate in some cases; however, must be individualized based on patient's comorbidities and likelihood of cure.
Medical management only	3	May be palliative care in a terminal patient.
Permanent biliary metallic stent	5	
Removable biliary covered stent	5	
Endosonography-guided biliary drainage (ESBD)	4	
<u>Rating Scale:</u> 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Variant 4: Initial therapeutic procedure for a patient with hilar biliary obstruction from malignant etiology (e.g., Klatskin tumor).

Treatment/Procedure	Rating	Comments
Endoscopic internal biliary catheter	6	
Percutaneous internal/external biliary catheter	8	
<u>Rating Scale:</u> 1 2 3 Usually not appropriate; 4 5 6 May be appropriate; 7 8 9 Usually appropriate		

Treatment/Procedure	Rating	Comments
Surgery (transplant or hepaticojunostomy)	5	May be appropriate in some cases; however, must be individualized based on patient's comorbidities and likelihood of cure.
Medical management only	2	
Permanent biliary metallic stent	6	
Removable biliary covered stent	5	
Endosonography-guided biliary drainage (ESBD)	3	
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Variant 5: Initial therapeutic procedure for a patient with elevated bilirubin and dilated bile ducts from unknown etiology.

Treatment/Procedure	Rating	Comments
Endoscopic internal biliary catheter	8	
Percutaneous internal/external biliary catheter	7	Most appropriate whenever endoscopic treatment is unsuccessful.
Surgery (transplant or hepaticojunostomy)	2	
Medical management only	2	
Permanent biliary metallic stent	1	
Removable biliary covered stent	3	
Endosonography-guided biliary drainage (ESBD)	3	
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Variant 6: Initial therapeutic procedure for a patient with dilated bile ducts and coagulopathy (international normalized ratio [INR] >2.0 and/or platelet count <60 K).

Treatment/Procedure	Rating	Comments
Endoscopic internal biliary catheter	8	
Percutaneous internal/external biliary catheter	6	Most appropriate whenever endoscopic treatment is unsuccessful and after attempting to correct coagulopathy.
Surgery (transplant or hepaticojunostomy)	2	
Medical management only	4	
Permanent biliary metallic stent	1	
Removable biliary covered stent	2	
Endosonography-guided biliary drainage (ESBD)	3	
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Variant 7: Initial therapeutic procedure for a patient with dilated bile ducts and moderate to massive ascites.

Treatment/Procedure	Rating	Comments
Endoscopic internal biliary catheter	8	
Percutaneous internal/external biliary catheter	5	Most appropriate whenever endoscopic treatment is unsuccessful and after drainage of ascites.
Surgery (transplant or hepaticojejunostomy)	2	
Medical management only	4	Manage ascites prior to therapeutic intervention.
Permanent biliary metallic stent	2	
Removable biliary metallic stent	4	
Endosonography-guided biliary drainage (ESBD)	3	
<u>Rating Scale:</u> 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Variant 8: Initial therapeutic procedure for a patient with dilated bile ducts and suspected biliary sepsis/acute cholangitis.

Treatment/Procedure	Rating	Comments
Endoscopic internal biliary catheter	8	
Percutaneous internal/external biliary catheter	8	
Surgery (transplant or hepaticojejunostomy)	2	
Medical management only	2	
Permanent biliary metallic stent	1	
Removable biliary covered stent	2	
Endosonography-guided biliary drainage (ESBD)	4	
<u>Rating Scale:</u> 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Variant 9: Initial therapeutic procedure for a liver transplant recipient with elevated bilirubin and suspected biliary anastomotic stenosis and/or bile leak, with no dilated ducts.

Treatment/Procedure	Rating	Comments
Endoscopic internal biliary catheter	8	Individualize based on local expertise and patient anatomy.
Percutaneous internal/external biliary catheter	8	
Surgery (transplant or hepaticojejunostomy)	3	Typically not appropriate as the initial treatment. However, may be needed as a definitive therapy.
Medical management only	2	
Permanent biliary metallic stent	1	
Removable biliary covered stent	5	Depends on accessibility endoscopically.
<u>Rating Scale:</u> 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

(ESBD) Treatment/Procedure	Rating	Comments
Rating Scale: Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Variant 10: Initial therapeutic procedure for a patient with bile leak and dilated bile ducts following laparoscopic cholecystectomy.

Treatment/Procedure	Rating	Comments
Endoscopic internal biliary catheter	8	
Percutaneous internal/external biliary catheter	8	Most appropriate whenever endoscopic treatment is unsuccessful and after drainage of ascites.
Surgery (transplant or hepaticojejunostomy)	4	
Medical management only	1	
Permanent biliary metallic stent	1	
Removable biliary covered stent	1	
Endosonography-guided biliary drainage (ESBD)	1	
Rating Scale: Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Summary of Literature Review

Since the late 1970s, percutaneous biliary drainage has been used in the management of jaundice caused by malignant and benign biliary obstruction. In the setting of acute cholangitis, percutaneous decompression of an obstructed biliary system can be lifesaving. For patients with cancer who are receiving chemotherapy, untreated obstructive jaundice leads to biochemical derangements that often preclude continuation of therapy unless biliary decompression is performed (see the National Guideline Clearinghouse [NGC] summary [ACR Appropriateness Criteria® jaundice](#)).

Diagnostic Imaging

Diagnostic studies are used to identify the underlying etiology of clinical jaundice, confirm the presence and extent of a mechanical obstruction, and exclude extrahepatic metastatic disease. Accurate preoperative identification of the location and extent of the underlying cause of the obstructive jaundice is most beneficial in planning surgical or interventional treatment. Noninvasive diagnostic imaging includes ultrasound (US), helical computerized tomography (CT), and magnetic resonance cholangiopancreatography (MRCP).

Over the past two decades, CT and US have been the primary imaging tools in the evaluation of bile duct pathology. Preoperative imaging of the liver and surrounding structures has improved the identification of the extrahepatic spread of tumor and invasion of the portal vein/hepatic artery, thereby greatly assisting with presurgical planning. With advances in CT technology, helical CT imaging has achieved marked improvement in anatomic detail, providing exceptional imaging of the liver, bile ducts, and periportal area. MRCP provides excellent imaging of bile duct segments allowing more detailed, three-dimensional imaging of the entire biliary system. As with Klatskin type lesions, MRCP allows visualization of isolated bile duct segments that no longer communicate with the main biliary system and may not be visualized with either percutaneous transhepatic cholangiography (PTC) or endoscopic retrograde cholangiopancreatography (ERCP).

PTC and ERCP are invasive diagnostic procedures and are most often performed during placement of a percutaneous or endoscopic biliary drainage catheter or stent. Since these two procedures gain access to the biliary system, they also may allow further diagnostic tests to be performed (e.g., bile cytology, bile duct biopsies, intraductal US, and PTC).

Endoscopic Versus Percutaneous Drainage

With the availability of percutaneous, endoscopic, and surgical approaches, the selection of the most appropriate modality with which to provide biliary drainage will largely depend on the interventional options available to the patient at the time of presentation. For those who are not surgical candidates due to nonresectability of disease or to comorbidities, the choice of percutaneous versus endoscopic route may largely depend on the location and extent of the obstructing lesion in addition to the expertise of the operator.

In recent years, endoscopic retrograde biliary drainage (ERBD) has overtaken percutaneous transhepatic biliary drainage (PTBD) as the initial procedure of choice in patients with distal bile duct obstructions. Much of this trend can be attributed to the availability of trained gastroenterologists at most institutions and reported lower complication rates with ERBD. In contrast, some authors have recommended that patients with hilar neoplasm (Klatskin tumor) may be better managed by the percutaneous approach. These publications note that ERBD too often provides ineffective drainage of isolated bile duct segments that become opacified during ERCP and, as a result, develop biliary sepsis.

Contraindications to PTBD are relatively few but might include severe coagulopathy or ascites. Absolute contraindications to ERBD would include pharyngeal or esophageal obstruction or active coagulopathy. Relative contraindications to ERBD might include acute pancreatitis, severe cardiopulmonary disease, and previous Roux-en-Y surgery.

The use of endoscopic US to guide ERBD in patients with difficult anatomy and/or after failed attempts at endoscopic cannulation of the ampulla of Vater has been described in recent literature. Studies have described the successful placement of biliary drainage catheters using the transgastric or transduodenal approach. Although this approach may offer access to the biliary ducts in patients whose anatomy precludes routine endoscopic placement of drainage catheters/stents via the ampulla of Vater, this approach requires a higher level of endoscopic skills and experience not routinely seen outside of major medical centers and teaching facilities. Although this technique may provide an important alternative to percutaneous drainage catheters, further well-conducted studies are needed.

Preoperative Biliary Drainage

Percutaneous and endoscopic biliary decompression prior to surgery has been performed for many years. When surgery is delayed, percutaneous or endoscopic drainage of an obstructed biliary system not only relieves the associated symptoms of jaundice (e.g., nausea, pruritus) but also helps to correct the biochemical derangements caused by prolonged biliary obstruction. Preoperative drainage allows time for surgical planning, detailed imaging, and proper laboratory testing. Correction of nutritional and biochemical derangements prior to surgery may result in improved surgical outcomes.

The surgical and clinical benefits of preoperative biliary drainage, however, remain questionable, and its benefits have been widely debated. External biliary drainage alone does not allow the bile salts to return to the gastrointestinal system, thereby potentially causing severe metabolic alterations. Early randomized trials assessing the benefits of preoperative external biliary drainage failed to demonstrate any reduction in surgical morbidity. In contrast, internal biliary drainage, by alleviating cholestasis without loss of bile salts, has been shown to improve postoperative results. In 1987, a group of investigators published a prospective randomized study demonstrating the benefits of preoperative internal biliary drainage by reducing surgical mortality rate from 10% to 0% and associated morbidity from 70% to 16%. Other investigators have published trials in support of these findings. In contrast, several studies have reported an increase in postoperative complications, especially infection rates, following preoperative biliary drainage. The increase in postoperative infections was attributed to the contamination of the sterile bile from direct communication with skin and gut flora following percutaneous and endoscopic drainage. A meta-analysis in 2002 failed to show any positive or adverse effect of preoperative endoscopic stenting prior to pancreaticoduodenectomy. More recent literature has suggested that selective biliary drainage of the remnant liver as opposed to total biliary drainage in conjunction with portal vein embolization prior to an extended hemihepatectomy can significantly promote hypertrophy of the future remnant liver segment.

Plastic Versus Metal Stents for Malignant Disease

The choice of plastic or metallic stents for the optimal percutaneous or endoscopic palliation of patients with nonresectable malignant biliary obstruction is not clear. Metallic stents have been shown to be more cost-effective, with fewer reinterventions needed when placed in patients with life expectancies of 6 to 12 months. Metallic stents also provide a better quality of life for the terminally ill patient by eliminating the need to care for an external prosthesis. The long-term patency of metallic stents, on the other hand, is not good, with an occlusion rate of 30% to 40% by 6 months, and nearly all patients requiring reintervention within a year.

Although there are no clear data in the literature, the temporary use of plastic stents may be preferable in cases of obstructive lesions that may respond to chemotherapy/radiotherapy (e.g., lymphoma), in patients who have hilar lesions with multiple isolated biliary segments, or in patients where a histological diagnosis has yet to be made.

The use of polytetrafluoroethylene (PTFE)-covered self-expandable stents in the treatment of malignant biliary obstruction has been demonstrated to provide better patency rates than metallic noncovered stents and offer the option of removal if occluded. Further studies are needed, as this approach is undergoing preliminary evaluation to identify which patient populations will most benefit. The use of drug-eluting or dissolving stents is also under investigation.

Metal Stenting in Benign Disease

The use of metallic biliary stents for malignant biliary obstruction has been well accepted, especially for inoperable patients whose life expectancies

are 6 to 12 months. The use of permanent metallic stents to treat benign strictures of the biliary tree (e.g., bile duct strictures from chronic pancreatitis, postoperative bilioenteric anastomotic strictures) has been described in the literature but remains highly controversial. Some studies have shown very poor clinical results, with short-term patency and a need for extensive surgery to correct the eventual biliary obstruction. To date there is not enough evidence in the literature to support the use of permanent metallic stents to treat benign biliary strictures, especially in cases where surgical revision remains an option, and percutaneous treatment by balloon dilatation and long-term internal/external drainage has proven to be effective and safe. The use of covered metal stents in benign biliary disease provides additional options for patients who are not optimal surgical candidates. The temporary placement of fully covered metallic stents in benign biliary strictures has been shown to have good results, with 83% resolution of the benign stricture by 3.3 months and an associated complication rate of only 14%.

Liver Transplant/Postoperative Dilatation

Biliary complications following orthotopic liver transplantation (OLT) are an important cause of graft loss and are associated with significant morbidity and mortality. The incidence of biliary complications is between 17% and 25%, of which over half are caused by biliary stricture. Bile ducts in the transplanted liver are extremely sensitive to injury, typically as a result of injury to the hepatic artery; ischemic injury to the bile ducts can manifest as biliary stricture and/or bile leak. It is notable that even in the case of significant obstruction or stricture of the biliary anastomosis, the bile ducts within a transplanted liver often fail to dilate.

The failure rate of PTC is reportedly higher in nondilated systems (35%) as compared to dilated systems (5%). In a study of 117 patients, the technical success rate using a 21-gauge needle and a 0.018-inch wire to gain initial access into a nondilated biliary system was 90%, with a major complication rate of only 4%. Following OLT, biliary strictures can be found in two forms: anastomotic and nonanastomotic or diffuse biliary strictures. Anastomotic strictures have a better prognosis and can be treated with percutaneous or endoscopic biliary drainage followed with repeated biliary dilatations. Occasionally, anastomotic strictures will require reoperation. Nonanastomotic or diffuse biliary strictures are multiple and often require retransplantation. Independent of the underlying etiology, early diagnosis and intervention following OLT increase patient survival. The use of endoscopic and/or percutaneous transhepatic therapy has proven to be effective in the management of anastomotic and nonanastomotic strictures and biliary leaks following liver transplantation.

Complications of Percutaneous Biliary Drainage

Percutaneous biliary drainage is one of the most challenging procedures performed by interventional radiologists. The reported technical success rate of PTC/PTBD is between 90% and 95%. Related periprocedural mortality rates of 0.7% to 8.6% have been reported. Drainage-related complications such as hemorrhage (3%–7%), acute sepsis (3%–5%), and pleural transgression (1%–5%) can occur during the placement of the catheter. Delayed complications such as pericatheter bile leak (15%–20%), catheter dislodgement (10%–20%), catheter obstruction with or without cholangitis (47%), and tumor spread along the catheter tract have been described weeks to months following catheter placement.

One of the most frequent complications associated with biliary drainage is cholangitis. It has been reported to occur in up to 47% of patients treated. The pathophysiology behind the development of cholangitis following biliary drainage is complex and has been described in the literature. The use of larger catheter size has been shown to reduce the incidence of catheter obstruction and catheter-related cholangitis. The use of choleretics, oral antibiotics, antibiotic-impregnated stents, and frequent biliary catheter exchanges have all been recommended to decrease biliary catheter occlusions and recurrent cholangitis.

Summary

- Endoscopic biliary drainage is generally considered the best initial therapeutic procedure when biliary drainage is necessary.
- PTC for biliary drainage has evolved over the past three decades and has established itself as an important diagnostic tool and treatment modality in the management of patients with malignant and nonmalignant obstructive jaundice.
- The choice between percutaneous (PTC/PTBD), endoscopic, or surgical therapy will greatly depend on the clinical status (comorbidities) of the patient, the etiology and extent of the biliary pathology, and the expertise of the clinical specialist. The choice between percutaneous biliary drainage techniques and endoscopic or surgical techniques will vary from institution to institution depending on operator expertise.
- In nonoperable biliary obstruction, endoscopic drainage is recommended. If it is unavailable or has failed, percutaneous drainage procedure is recommended.
- Although the use of permanent metallic stents in malignant biliary disease is well accepted. Its use in benign disease is not. The temporary use of removable covered stents for benign biliary strictures may play an important role.
- The best therapeutic management of patients with biliary obstruction involves a team approach leveraging the experience and expertise of the primary physician, interventional radiologists, gastroenterologists, and surgeons.

Clinical Algorithm(s)

Algorithms were not developed from criteria guidelines.

Scope

Disease/Condition(s)

Benign and malignant biliary obstruction

Guideline Category

Management

Treatment

Clinical Specialty

Gastroenterology

Oncology

Radiology

Surgery

Intended Users

Health Plans

Hospitals

Managed Care Organizations

Physicians

Utilization Management

Guideline Objective(s)

To evaluate the appropriateness of initial therapeutic procedures in the radiologic management of benign and malignant biliary obstructions

Target Population

Patients with benign or malignant biliary obstruction

Interventions and Practices Considered

1. Endoscopic internal biliary catheter
2. Percutaneous internal/external biliary catheter
3. Surgery (transplant or hepaticojejunostomy)
4. Medical management only
5. Permanent biliary metallic stent
6. Removable biliary covered stent

7. Endosonography-guided biliary drainage (ESBD)

Major Outcomes Considered

- Utility of percutaneous biliary drainage in the treatment of malignant biliary obstruction
- Morbidity or mortality associated with malignant biliary obstruction
- Quality of life
- Complications of percutaneous biliary drainage

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Literature Search Procedure

The Medline literature search is based on keywords provided by the topic author. The two general classes of keywords are those related to the condition (e.g., ankle pain, fever) and those that describe the diagnostic or therapeutic intervention of interest (e.g., mammography, MRI).

The search terms and parameters are manipulated to produce the most relevant, current evidence to address the American College of Radiology Appropriateness Criteria (ACR AC) topic being reviewed or developed. Combining the clinical conditions and diagnostic modalities or therapeutic procedures narrows the search to be relevant to the topic. Exploding the term "diagnostic imaging" captures relevant results for diagnostic topics.

The following criteria/limits are used in the searches.

1. Articles that have abstracts available and are concerned with humans.
2. Restrict the search to the year prior to the last topic update or in some cases the author of the topic may specify which year range to use in the search. For new topics, the year range is restricted to the last 5 years unless the topic author provides other instructions.
3. May restrict the search to Adults only or Pediatrics only.
4. Articles consisting of only summaries or case reports are often excluded from final results.

The search strategy may be revised to improve the output as needed.

Number of Source Documents

The total number of source documents identified as the result of the literature search is not known.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Strength of Evidence Key

Category 1 - The conclusions of the study are valid and strongly supported by study design, analysis, and results.

Category 2 - The conclusions of the study are likely valid, but study design does not permit certainty.

Category 3 - The conclusions of the study may be valid, but the evidence supporting the conclusions is inconclusive or equivocal.

Category 4 - The conclusions of the study may not be valid because the evidence may not be reliable given the study design or analysis.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

The topic author drafts or revises the narrative text summarizing the evidence found in the literature. American College of Radiology (ACR) staff draft an evidence table based on the analysis of the selected literature. These tables rate the strength of the evidence for all articles included in the narrative text.

The expert panel reviews the narrative text, evidence table, and the supporting literature for each of the topic-variant combinations and assigns an appropriateness rating for each procedure listed in the table. Each individual panel member forms his/her own opinion based on his/her interpretation of the available evidence.

More information about the evidence table development process can be found in the ACR Appropriateness Criteria® Evidence Table Development document (see the "Availability of Companion Documents" field).

Methods Used to Formulate the Recommendations

Expert Consensus (Delphi)

Description of Methods Used to Formulate the Recommendations

Modified Delphi Technique

The appropriateness ratings for each of the procedures included in the Appropriateness Criteria topics are determined using a modified Delphi methodology. A series of surveys are conducted to elicit each panelist's expert interpretation of the evidence, based on the available data, regarding the appropriateness of an imaging or therapeutic procedure for a specific clinical scenario. American College of Radiology (ACR) staff distributes surveys to the panelists along with the evidence table and narrative. Each panelist interprets the available evidence and rates each procedure. The surveys are completed by panelists without consulting other panelists. The ratings are a scale between 1 and 9, which is further divided into three categories: 1, 2, or 3 is defined as "usually not appropriate"; 4, 5, or 6 is defined as "may be appropriate"; and 7, 8, or 9 is defined as "usually appropriate." Each panel member assigns one rating for each procedure per survey round. The surveys are collected and the results are tabulated, de-identified and redistributed after each round. A maximum of three rounds are conducted. The modified Delphi technique enables each panelist to express individual interpretations of the evidence and his or her expert opinion without excessive bias from fellow panelists in a simple, standardized and economical process.

Consensus among the panel members must be achieved to determine the final rating for each procedure. Consensus is defined as eighty percent (80%) agreement within a rating category. The final rating is determined by the median of all the ratings once consensus has been reached. Up to three rating rounds are conducted to achieve consensus.

If consensus is not reached, the panel is convened by conference call. The strengths and weaknesses of each imaging procedure that has not reached consensus are discussed and a final rating is proposed. If the panelists on the call agree, the rating is accepted as the panel's consensus. The document is circulated to all the panelists to make the final determination. If consensus cannot be reached on the call or when the document is circulated, "No consensus" appears in the rating column and the reasons for this decision are added to the comment sections.

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

Metallic stents have been shown to be more cost-effective than plastic stents, with fewer reinterventions needed when placed in patients with life expectancies of 6-12 months.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

Criteria developed by the Expert Panels are reviewed by the American College of Radiology (ACR) Committee on Appropriateness Criteria.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The recommendations are based on analysis of the current literature and expert panel consensus.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate radiologic management of patients with benign and malignant biliary obstruction

Potential Harms

Complications of Percutaneous Biliary Drainage

- Percutaneous biliary drainage is one of the most challenging procedures performed by interventional radiologists. The reported technical success rate of percutaneous transhepatic cholangiography/percutaneous transhepatic biliary drainage (PTC/PTBD) is between 90% and 95%. Related periprocedural mortality rates of 0.7% to 8.6% have been reported. Drainage-related complications such as hemorrhage (3%–7%), acute sepsis (3%–5%), and pleural transgression (1%–5%) can occur during the placement of the catheter. Delayed complications such as pericatheter bile leak (15%–20%), catheter dislodgement (10%–20%), catheter obstruction with or without cholangitis (47%), and tumor spread along the catheter tract have been described weeks to months following catheter placement.
- One of the most frequent complications associated with biliary drainage is cholangitis. It has been reported to occur in up to 47% of patients treated. The pathophysiology behind the development of cholangitis following biliary drainage is complex and has been described in the literature. The use of larger catheter size has been shown to reduce the incidence of catheter obstruction and catheter-related cholangitis. The use of choleretics, oral antibiotics, antibiotic-impregnated stents, and frequent biliary catheter exchanges have all been recommended to decrease biliary catheter occlusions and recurrent cholangitis.

Complications of Liver Transplant

Biliary complications following orthotopic liver transplantation (OLT) are an important cause of graft loss and are associated with significant morbidity and mortality. The incidence of biliary complications is between 17% and 25%, of which over half are caused by biliary stricture. Bile ducts in the transplanted liver are extremely sensitive to injury, typically as a result of injury to the hepatic artery; ischemic injury to the bile ducts can manifest as biliary stricture and/or bile leak. It is notable that even in the case of significant obstruction or stricture of the biliary anastomosis, the bile ducts within a transplanted liver often fail to dilate.

Contraindications

Contraindications

- Contraindications to percutaneous transhepatic biliary drainage (PTBD) are relatively few but might include severe coagulopathy or ascites.
- Absolute contraindications to endoscopic retrograde biliary drainage ERBD would include pharyngeal or esophageal obstruction or active coagulopathy. Relative contraindications to ERBD might include acute pancreatitis, severe cardiopulmonary disease, and previous Roux-en-Y surgery.

Qualifying Statements

Qualifying Statements

The American College of Radiology (ACR) Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists, and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those examinations generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the U.S. Food and Drug Administration (FDA) have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Identifying Information and Availability

Bibliographic Source(s)

Bibliographic Source(s)

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Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

1996 (revised 2012)

Guideline Developer(s)

American College of Radiology - Medical Specialty Society

Source(s) of Funding

The American College of Radiology (ACR) provided the funding and the resources for these ACR Appropriateness Criteria®.

Guideline Committee

Committee on Appropriateness Criteria, Expert Panel on Interventional Radiology

Composition of Group That Authored the Guideline

Panel Members: Charles E. Ray, Jr, MD, PhD (*Panel Chair*); Jonathan M. Lorenz, MD (*Panel Vice-chair*); Charles T. Burke, MD; Michael D. Darcy, MD; Nicholas Fidelman, MD; Frederick L. Greene, MD; Eric J. Hohenwalter, MD; Thomas B. Kinney, MD; Kenneth J. Kolbeck, MD; Jon K. Kostelic, MD; Brian E. Kouri, MD; Ajit V. Nair, MD; Charles A. Owens, MD; Paul J. Rochon, MD; Don C. Rockey, MD; George Vatakencherry, MD

Financial Disclosures/Conflicts of Interest

Not stated

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Owens CA, Funaki BS, Ray CE Jr, Brown DB, Gemery JM, Greene FL, Kinney TB, Kostelic JK, Lorenz JM, Millward SF, Nemcek AA Jr, Reinhart RD, Rockey DC, Silberzweig JE, Vatakencherry G, Expert Panel on Interventional Radiology. ACR Appropriateness Criteria® percutaneous biliary drainage in benign and malignant biliary obstruction. [online publication]. Reston (VA): American College of Radiology (ACR); 2008. 7 p.

Guideline Availability

Electronic copies: Available from the [American College of Radiology \(ACR\) Web site](#) .

Print copies: Available from the American College of Radiology, 1891 Preston White Drive, Reston, VA 20191. Telephone: (703) 648-8900.

Availability of Companion Documents

The following are available:

- ACR Appropriateness Criteria®. Overview. Reston (VA): American College of Radiology; 2 p. Electronic copies: Available in Portable Document Format (PDF) from the [American College of Radiology \(ACR\) Web site](#) .
- ACR Appropriateness Criteria®. Literature search process. Reston (VA): American College of Radiology; 1 p. Electronic copies: Available in PDF from the [ACR Web site](#) .
- ACR Appropriateness Criteria®. Evidence table development – diagnostic studies. Reston (VA): American College of Radiology; 2013 Nov. 3 p. Electronic copies: Available in PDF from the [ACR Web site](#) .
- ACR Appropriateness Criteria®. Evidence table development – therapeutic studies. Reston (VA): American College of Radiology; 2013 Nov. 4 p. Electronic copies: Available in PDF from the [ACR Web site](#) .
- ACR Appropriateness Criteria® radiologic management of benign and malignant biliary obstruction. Evidence table. Reston (VA): American College of Radiology; 26 p. Electronic copies: Available from the [ACR Web site](#) .

Patient Resources

None available

NGC Status

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